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MERCK & CO., INC. and Defendants and Counterclaimants
MERCK SHARP & DOHME CORP. and ISIS PHARMACEUTICALS, INC.

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

GILEAD SCIENCES, INC.,

Plaintiff and Counterdefendant,

v.

MERCK & CO., INC. (Defendant only), MERCK SHARP & DOHME CORP., and ISIS PHARMACEUTICALS, INC.

Defendants and Counterclaimants.

Case No. 5:13-cv-04057-BLF

DEFENDANTS' [PROPOSED] FINDINGS OF FACT AND CONCLUSIONS OF LAW

Date: March 29, 2016
Time: 9.00 a.m.
Place: Courtroom 3 — 5th Floor
Before: The Honorable Beth Labson Freeman

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I. THE PARTIES

1. Gilead Sciences, Inc. ("Plaintiff" or "Gilead") and Defendants Merck & Co., Inc. ("Merck & Co."), Merck Sharp & Dohme Corp ("MSD Corp."), and Ionis Pharmaceuticals, Inc. ("Ionis"), formerly known as Isis Pharmaceuticals, Inc., (collectively, "Defendants" or "Merck") are the parties that appeared at trial.

2. Plaintiff Gilead is a company organized and existing under the laws of the State of Delaware with its principal place of business at 333 Lakeside Drive, Foster City, California 94404.

3. Merck & Co. is a company organized under the laws of the State of New Jersey with its principal place of business at One Merck Drive, P.O. Box 100, Whitehouse Station, NJ 08889-0100.

4. MSD Corp. is a company organized under the laws of the State of New Jersey with its principal place of business at One Merck Drive, P.O. Box 100, Whitehouse Station, NJ 08889-0100.

5. MSD Corp. is a subsidiary of Merck & Co.

6. Ionis is a company organized under the laws of the State of Delaware with its principal place of business at 2855 Gazelle Court, Carlsbad, CA 92010.

II. BACKGROUND OF THE CASE

7. The patents-in-suit are U.S. Patent Nos. 7,105,499 (the "'499 Patent") and 8,481,712 (the "'712 Patent"), and the following claims are asserted by Merck:

Patent	Asserted Claims
'499 Patent	1 and 2
'712 Patent	1, 2, 3, 5, 7, 9, 10 and 11

8. On February 2, 2016, the Court granted summary judgment that the asserted claims of the patents-in-suit are all infringed by the sale by Plaintiff Gilead Sciences, Inc. ("Gilead") of its accused products (SOVALDI and HARVONI) containing the active pharmaceutical ingredient "sofosbuvir." ECF No. 214.

9. From March 7-16, 2016 this Court held an eight-day jury trial on Gilead's legal defenses under 35 U.S.C. § 112 (written description and lack of enablement) and § 102 (derivation and prior

inventorship). On March 22, 2016, the jury returned a unanimous verdict finding all the asserted claims not invalid for lack of written description or lack of enablement. A jury trial on damages began on March 22, 2016.

10. A bench trial is scheduled to begin on March 29, 2016 to address equitable defenses asserted by Gilead[1]. In the Joint Pretrial Statement and Order (ECF 229), the parties identified the issues as follows:

- Waiver. Waiver requires that a patentholder, with full knowledge of the material facts, intentionally relinquish its patent enforcement rights or act in a manner that is so inconsistent with an intent to enforce its rights as to induce a reasonable belief that such right has been relinquished.
- Unclean hands. A showing of unclean hands requires that one coming for relief have committed some unconscionable act immediately and necessarily related to the equity that he seeks in respect of the matter in litigation.

11. Gilead's defense of waiver must fail because on multiple occasions between 2001 and 2011, 1) Merck explicitly informed Pharmasset (now a Gilead subsidiary) that it required a license from Merck to sell its products-in-development; 2) Pharmasset internally acknowledged that it understood Merck would assert its patent rights against Pharmasset unless Pharmasset obtained a license from Merck; 3) in 2004, Merck informed Pharmasset that Merck would not pay Pharmasset for a license to PSI-6130 because that compound was already "in Merck's stable" as a result of Merck's IP; 4) Pharmasset repeatedly sought a license from Merck in 2008; and 5) in 2010, Merck executives explicitly told Pharmasset's CEO that Pharmasset's compound under development (PSI-7977) would infringe Merck's IP rights if Pharmasset brought PSI-7977 to market without a license from Merck.

12. Gilead's defense of unclean hands is precluded by the jury verdict. Even if not so precluded, the unclean hands defense must fail because 1) Merck's patent applications – as filed on January 18, 2002 – covered the compound that Gilead now contends Merck wrongfully claimed after March 17, 2004; 2) the Merck-Pharmasset Confidentiality Agreement explicitly excluded from its ambit

[1] On March 21, 2016, Gilead withdrew its defense that claims 1 and 2 of the '499 Patent are invalid for indefiniteness, as well as its equitable defenses of laches and equitable estoppel.

information that Pharmasset made public; 3) upon being informed of the structure of PSI-6130 on March 17, 2004, Merck's patent attorney – Dr. Durette – took no action to prosecute the '499 patent starting March 17, 2004 until after January 13, 2005, when Pharmasset publicly disclosed the structure of PSI-6130 in the published Clark patent application; 4) Pharmasset's public disclosure of the structure of PSI-6130 on January 13, 2005 immediately caused that information to cease being confidential information under the Merck-Pharmasset confidentiality agreement; 5) weeks after the structure of PSI-6130 was made public, which removed any confidentiality obligation imposed on Dr. Durette, Merck filed its Second Preliminary Amendment on February 9, 2005; 6) Merck's Second Preliminary Amendment did not expand the scope of Merck's claims to newly-cover PSI-6130 but rather narrowed their scope to aid in speedy prosecution; 7) any activity by Dr. Durette with regard to the prosecution of the '499 patent is irrelevant to the prosecution of the '712 patent by a different Merck patent attorney; and 8) Pharmasset publicly disclosed the structure of sofosbuvir in 2010, long before Merck obtained allowance of the claims of the '712 patent that covers the metabolites of sofosbuvir.

III. PATENTS-IN-SUIT

A. THE '499 Patent

13. The patent application that ultimately issued as the '499 Patent issued from PCT/US02/01531filed on January 18, 2002.

14. The '499 Patent claims priority to U.S. Provisional Patent Application No. 60/344,528, filed on October 25, 2001; U.S. Provisional Patent Application No. 60/299,320, filed on June 19, 2001; U.S. Provisional Patent Application No. 60/282,069, filed April 6, 2001; and U.S. Provisional Patent Application No. 60/263,313, filed on January 22, 2001.

15. The '499 Patent recites: "[t]he present invention provides nucleoside derivatives which are inhibitors of RNA-dependent RNA viral polymerase. These compounds are inhibitors of RNA-dependent RNA viral replication and are useful for the treatment of RNA-dependent RNA viral infection. They are particularly useful as inhibitors of hepatitis C virus (HCV) NS5B polymerase, as inhibitors of HCV replication, and for the treatment of hepatitis C infection." (ECF 1-1, col. 1, Summary of the Invention).

16. The specification defines the term administration as follows: "[t]he terms 'administration

of' and 'administering a' compound should be understood to mean providing a compound of the invention or a prodrug of a compound of the invention to the individual in need." (ECF1-1, col. 32, lines 5-8).

17. The specification of the '499 Patent recites "[i]t has now been found that nucleoside compounds of the present invention and certain derivatives thereof are potent inhibitors of RNA-dependent RNA viral replication and in particular HCV replication. The 5'-triphosphate derivatives of the nucleoside compounds are inhibitors of RNA-dependent RNA viral polymerase and in particular HCV NS5B polymerase. The instant nucleoside compounds and derivatives thereof are useful to treat RNA-dependent RNA viral infection and in particular HCV infection. It is therefore an object of the present invention to provide nucleoside compounds and certain derivatives thereof which are useful as inhibitors of RNA-dependent RNA viral polymerase and in particular as inhibitors of HCV NS5B polymerase. It is another object of the present invention to provide nucleoside derivatives which are useful as inhibitors of the replication of an RNA-dependent RNA virus and in particular as inhibitors of the replication of hepatitis C virus." (ECF 1-1, col. 2, lines 32-49).

18. The specification of the '499 Patent recites: "[i]t is another object of the present invention to provide nucleoside compounds and certain derivatives which are useful in the treatment of RNA-dependent RNA viral infection and in particular in the treatment of HCV infection." (ECF 1-1, col. 2, lines 50-53).

19. The specification of the '499 Patent recites: "[t]he terms 'administration of' and 'administering a' compound should be understood to mean providing a compound of the invention or a prodrug of a compound of the invention to the individual in need." (ECF 1-1, col. 32, lines 5-8).

20. The '499 Patent incorporates in its entirety a reference by Wagner, C., Iyer, V., McIntee, E. "Pronucleotides: Toward the In Vivo Delivery of Antiviral and Anticancer Nucleotides" Med. Res. Rev., 20: 417-451, 2000; "Wagner"). (ECF1-1, col. 77, lines 60-63; col. 87, lines 51-54; Ex. 24).

21. Wagner discusses several classes of nucleotide prodrugs for in vivo delivery of antiviral and anticancer nucleotides. These include alkyl and aryl phosphate derivatives, S-acyl-2-thiethyl ("SATE") prodrugs, phosphonomethoxy nucleoside prodrugs, and phosphoramidate prodrugs. (Ex. 24 at 419-442).

22. The ’499 Patent also incorporates in its entirety by reference U.S. Patent Nos. 5,770,725, 5,849,905, and 6,020,482. (ECF 1-1, col. 77, lines 64-67).

23. The ’499 Patent also incorporates in its entirety by reference U.S. Patent Nos. 5,922,695, 5,977,089, 6,043,230, and 6,069,249. (ECF 1-1, col. 87, lines 54-57).

24. The ’499 Patent describes how to formulate candidate compounds for administration to a subject. (ECF 1-1 col. 33, line 31 - col. 35, line 38 and col. 136, lines 42-48).

25. The ‘499 Patent describes how to administer pharmaceutical formulations to a mammal infected with HCV (ECF 1-1 col. 35, line 39 - col. 36, line 13).

26. The ’499 Patent describes in vitro assays to test candidate compounds. (ECF 1-1, col. 132, line 1 - col. 136, line 40).

27. The ’499 Patent also discloses biological assays employed to measure the inhibition of HCV NS5B polymerase and HCV replication. (ECF 1-1, col. 132, line 1 to col. 133, line 23).

28. The ’499 Patent further describes a cytotoxicity assay and determination of in vitro antiviral activity. (ECF 1-1, cols. 134, line 53 to col. 136, line 40).

29. The ’499 Patent issued on September 12, 2006 to Merck and Ionis.

B. The ‘712 Patent

30. The patent application that ultimately issued as the’712 Patent issued U.S. Patent Application No. 11/701,682. (ECF 1-2 (cover page)).

31. The ‘712 Patent is a continuation of U.S. Patent Application No. 11/643,464, filed on December 21, 2006, which is a continuation of U.S. Patent Application No. 11/200,499, filed on August 9, 2005, which is a continuation of U.S. Patent Application No. 10/431,657, filed on May 7, 2003, which is a division of U.S. Patent Application No. 10/052,318, filed on January 18, 2002. (ECF 1-2 (cover page)).

32. The ‘712 Patent also claims priority to U.S. Provisional Patent Application No. 60/344,528, filed on October 25, 2001; U.S. Provisional Patent Application No. 60/299,320, filed on June 19, 2001; U.S. Provisional Patent Application No. 60/282,069, filed April 6, 2001; and U.S. Provisional Patent Application No. 60/263,313, filed on January 22, 2001. (ECF 1-2 (cover page)).

33. The specification of the application that issued as the ’712 Patent was a photocopy of its

predecessor specification as filed on January 18, 2002.

34. The '712 patent claims are directed to chemical compounds that are useful for treating HCV infection.

35. The '712 patent issued on July 9, 2013 to Merck and Ionis.

IV. WAIVER

A. Gilead Knew That PSI-6130 and PSI-7977 Was Covered by Merck's Intellectual Property

36. On May 23, 2003, after reviewing Merck's published patent application, Pharmasset proposed a potential chemical synthesis aimed at invalidating Merck's claim so that Pharmasset could have claims to PSI-6130. Ex. 1721.

37. On March 29, 2004, during a due diligence call between Ken Walton, Val Kamera and Doug Pon for Merck and Dr. Raymond Schinazi (Pharmasset's Executive Chairman), Alan Roemer, Bryce Roberts and Jeremy Clark for Pharmasset was explicitly told by Merck that Pharmasset did not have "freedom to operate" with regard to PSI-6130 because of Merck's IP. Ex. 2306.

38. On August 10, 2004, Pharmasset acknowledged that "Merck has potential I.P. in the same space and the value of their I.P. had to be taken into consideration. This would have resulted in a 50% reduction from the original offer." Ex. 1921.

39. On October 8, 2009, Pharmasset stated that "[a]ll things considered, Merck is the ideal strategic partner for PSI-7851 and Pharmasset. Consolidating nucleos(t)ide IP would lower the legal risk of this program…" Ex. 1770.

40. On May 25, 2010, in a potential cross-licensing proposal between Pharmasset and Merck, Pharmasset requested that Merck provide a "[n]on-exclusive, worldwide license under Merck patent rights and know how to develop, manufacture and commercialize products containing Licensed Compound [which included PSI-7977]." Ex. 1634.0003.

41. On June 16, 2010, Merck sent Pharmasset a counter-proposal that did not include a license from Merck to Pharmasset that would provide Pharmasset freedom-to-operate with regard to Pharmasset's HCV products. Ex. 1636.

42. On August 5, 2010, Pharmasset sent a second revised proposed deal to Merck that once again sought a license to Merck's patent estate, as follows: "[t]he licensing of Merck Patent Rights and Know-How is specific to the development, manufacture and commercialization of PSI-7977 as a Monotherapy Product, or as the PSI-7977 component of Pharmasset Combination Products." Ex. 1652. At this time, the '499 Patent had issued and the application that led to the '712 Patent was pending with the PTO.

43. In 2010, Merck executives informed Pharmsset's CEO P. Schaeffer Price that Pharmasset needed a license from Merck to commercialize PSI-7977. Mr. Price responded that he hoped Merck's attorney could "find the courthouse." Ex. 2392 at 116:05-06.

44. On May 27, 2011, Roche sent a letter to Pharmasset (Attn: Bryce Roberts) characterization previous interactions between the two companies in part as follows: "On September 8, 2010, Schaefer Price, you and others representing Pharmasset, including your outside IP counsel David Maxwell, met with Annette Weissbach, Peter Paciorek, Laura Berner, Dennis Tramaloni, Dirk Halbig and Brian Buckwalter in Nutley to discuss various issues under the Agreement. Roche raised the issue of Merck's '499 Patent Series and indicated it was our intention to ask Merck whether a deblocking license was available. At that time, David Maxwell suggested waiting until a decision came down in the arbitration with Emory University to clarify the availability of disabling art against the Merck patent. In a phone conversation among Dennis Tramaloni, David Maxwell and yourself shortly after the December 8, 2010 decision of the arbitration panel, David Maxwell acknowledged that the decision failed to provide the hoped for improvement of the prior art picture, at least against the U.S. patent within the '499 Series." Ex. 627.

45. In 2011, Roche (Pharmasset's development partner with regard to certain nucleosides) entered into a license agreement with Merck, whereby Merck granted Roche a license to the '499 patent (and other to-be-issued patents) and Roche agreed (among other things) to pay Merck a royalty of between 9-12%. Ex. 1783.

46. Under Roche's development agreement with Pharmasset, Pharmasset's consent to the Roche-Merck license was sought because Roche's royalty payments to Merck would reduce Roche's royalty payments to Pharmasset. Ex. 627.

47. By September 7, 2011, Phamasset consented to the Roche-Merck license. Ex. 2632.

B. Gilead Has Suffered No Prejudice Due to the Interactions between Merck and Pharmasset in 2004

48. A defense of waiver cannot be asserted based on any interaction between Merck and Pharmasset in 2004 because Merck's '499 patent did not issue until September 12, 2006.

49. Gilead's response to Merck's Interrogatory No. 11 (asking for the factual and legal basis for Gilead's defense that Merck's claims are barred by the equitable doctrine of laches and/or estoppel and/or waiver) does not point to any specific communications between Merck and Pharmasset, nor does Gilead's response specify any document that indicates Merck is estopped or has waived its right to assert the '499 and '712 patent against Gilead.

50. Gilead has presented no evidence that Merck has waived its right to assert the '499 and '712 patent against Gilead.

C. Gilead Knew That Merck Considered PSI-6130 Covered by Merck's Intellectual Property

51. In his 2010 deposition, Raymond Schinazi testified as follows: "[T]he two finalists were Merck and Roche, I believe, and then finally Merck stepped down when they found out what the structure was. They weren't very happy because they apparently had it in their patent as well, from what I understand." Trial Tr. 1151:10-16.

52. In his 2010 deposition, Raymond Schinazi testified as follows: "I don't remember exactly, but they were certainly concerned that we were basically licensing a compound they already had in their stable." Trial Tr. 1151:18-24.

53. In his 2010 deposition, Raymond Schinazi testified as follows: "They expressed it to us, verbally." Trial Tr. 1151:25-1152:1.

54. On October 10, 2008, Merck sent a letter to Pharmasset that stated that one of the benefits to Pharmasset of an acquisition by Merck includes "'[t]he ability to leverage Merck's intellectual property estate to reduce uncertainty and enhance the value of the Pharmsset assets going forward." Ex. 93.

55. On September 3, 2010, Merck again sent a letter that stated that one of the benefits to Pharmasset of an acquisition by Merck includes "'[t]he ability to leverage Merck's intellectual property

estate to reduce uncertainty and enhance the value of the Pharmsset assets going forward." Ex. 69.

56. Pharmasset was informed that Pharmasset's consent to the Merck-Roche license would cause the Merck-Roche license to spring into effect. Ex. 619.

D. Gilead Has Suffered No Prejudice Due to the Interactions between Merck and Pharmasset in 2010

57. Gilead points to Ex. 2314 (GILEAD00218105-07) as the only citation in response to Merck's Interrogatory No. 11 (asking for the factual and legal basis for Gilead's defense that Merck's claims are barred by the equitable doctrine of laches and/or estoppel and/or waiver) as alleged evidence that Merck delayed assertion of its patent rights, was misleading to Gilead or that Gilead has suffered material prejudice is misplaced.

58. Ex. 2314 is a letter from Merck to Pharmasset dated September 3, 2010 regarding the *licensing proposal provided to Merck by Pharmasset*. The letter rejects the licensing proposal and rather suggests the possibility that Merck acquires Pharmsset.

59. Ex. 2314 specifically puts Gilead on notice that Merck will assert its patent rights. In describing the benefits to Pharmasset and its shareholders in an acquisition of Pharmasset by Merck, the letter states one of the benefits is "[t]he ability to leverage Merck's intellectual property estate to reduce uncertainty and enhance the value of the Pharmasset assets going forward." Ex. 2314.0002. The very document cited by Gilead shows that Merck communicated to Gilead that Merck's intellectual property estate was a source of uncertainty for Gilead.

E. Pharmasset Has Suffered No Prejudice Due to Merck

60. Pharmasset was not harmed for any alleged reliance on not being sued by Merck; the company was purchased by Gilead for $11 billion. Ex. 1098.

F. Gilead has Suffered No Prejudice Due to Merck

61. Gilead was not harmed for any alleged reliance on not being sued by Merck; the company has over $23 billion in revenue from the sale of sofosbuvir drugs. Ex. 2668.

V. UNCLEAN HANDS

62. Claim 6 of U.S. Provisional Application No. 60/263,313, filed on January 22, 2001 (the earliest priority document for the '499 and '712 Patents) was directed to a method of inhibiting HCV

NS5B polymerase or inhibiting HCV replication by administering to a mammal a compound encompassed by a disclosed structural formula. The structural formula depicted in Claim 6 encompassed PSI-6130 – including a methyl up and a fluoro down at the 2' position of the sugar ring. Ex. 829.1025-1034.

63. The First Provisional Application was filed more than one year before Mr. Clark starting working on an HCV project in September or October of 2002 (Ex. 2383.0002 at 21.02-21.08), when Mr. Clark conceived of PSI-6130 in November of 2002 (Tr. Trans. 501:4-10) and when Mr. Clark first recorded PSI-6130 in his notebook on December 6, 2002 (Ex. 2383.0003 at 36.24-37.12).

64. The January 29, 2001 Non-Disclosure Agreement between Merck and Pharmasset stated "Confidential Information shall not, with respect to [Merck], include information which: (i) was lawfully in the possession of [Merck] prior to receiving the information from [Pharmasset]; or (ii) is in the public domain at the time of the disclosure or becomes part of the public domain other than by a breach of this Agreement or by other unlawful conduct of [Merck]; or (iii) is independently developed by [Merck] without reference to or reliance upon, directly or indirectly, any Confidential Information that is received pursuant to this Agreement and without any breach of the terms hereof; or (iv) is obtained in good faith from a third party not in privity to any of the Parties hereto, and provided said third party is not under any obligation of confidence or secrecy; or (v) is furnished to a third party by [Pharmasset] without disclosure restrictions on said third party similar to those set forth herein; or (vi) is ordered by a court of competent jurisdiction to be produced by [Merck]; provided that [Merck] first promptly notifies [Pharmasset] to limit the extent of Confidential Information that is required to be disclosed." Ex. 1238.

65. The claims in Merck's patent application generically covered PSI-6130 as filed in January 2002. Trial Tr. at 388:13-19. The preliminary amendment Dr. Durette filed on July 9, 2003 also covered PSI-6130. *Id*. at 393:6-394:15. After the 2004 phone call during which Pharmasset disclosed the structure of PSI-6130, he was aware that Merck's claims already covered that compound. *Id*. at 389:7-9. The Clark application that published in January 2005 disclosed PSI-6130 and together with data that showed this compound was "very active." *Id*. at 389:14-390:14. With the publication of the Clark application, Dr. Durette's obligations under the confidentiality agreement "terminated immediately." *Id*. at 390:15-22.

66. The October 23, 2003 Material Transfer Agreement between Pharmasset and Merck stated that "obligations of confidentiality shall not apply to information that: (1) is now or subsequently becomes generally available to the public through no wrongful act or omission of [Merck]; (2) [Merck] can demonstrate to have rightfully in its possession prior to disclosure to [Merck] by [Pharmasset]; (3) is independently developed by [Merck] without use, directly or indirectly, of any Confidential Information; or (4) [Merck] rightfully obtains from a third party who has the right to transfer or disclose it. Ex. 1231.

67. On December 12, 2003, an Amendment To Material Transfer Agreement between Pharmasset, Inc. and Merck & Co., Inc. was signed, adopting the confidentiality terms of the October 23, 2003 Material Transfer Agreement. Ex. 1231

68. On March 5, 2004, a Second Amendment to Material Transfer Agreement between Pharmasset, Inc. and Merck & Co., Inc. was signed, adopting the confidentiality terms of the October 23, 2003 Material Transfer Agreement. Ex. 1231.

69. On March 17, 2004, the structure of PSI-6130 was disclosed to Merck, including Dr. Durette. Ex. 2098.

70. The prosecution history of the '499 Patent shows that Merck took no action in the prosecution of the patent application leading to the '499 Patent between January 16, 2004 and February 7, 2005. Ex. 829.

71. On January 13, 2005, the Clark patent application published, publically disclosing PSI-6130. Ex. 155.

72. The information disclosed to Merck on March 17, 2004 was no longer confidential under the Second Amendment to Material Transfer Agreement between Pharmasset, Inc. and Merck & Co., Inc. once the Clark patent application published on January 13, 2005.

73. The February 7, 2005 amendment narrowed the subject matter in the claims, it did not claim anything that was not claimed in the non-provisional patent application filed on January 18, 2002. Ex. 829.

74. On April 18, 2005, Dr. Durette gave the Examiner permission to the Examiner to enter an Examiner's Amendment that would remove hydrogen from as on option for R^1 at the 2' position. Ex. 829.1103.

75. On May 5, 2005, the Examiner sent an Examiner's Amendment/Reasons For Allowance indicating that, as discussed in a telephonic interview, the Examiner would remove hydrogen from as on option for R^1 at the 2' position in an Examiner's Amendment. Ex. 829.1103.

76. The '499 Patent issued on September 12, 2006. ECF 1-1.

77. In 2010, Michael Sofia of Pharmasset, publically disclosed the structure of PSI-7977 (sofosbuvir) and that PSI-7977 was a development compound in human clinical trials. Ex. 2214.

78. The '712 Patent issued July 9, 2013. ECF 1-2.

DEFENDANTS' PROPOSED CONCLUSIONS OF LAW

I. EQUITABLE DEFENSES

A. The Binding Effect of the Jury Verdict

79. A jury trial on legal defenses should be determined prior to a bench trial on equitable defenses. *Dairy Queen, Inc. v. Wood*, 369 U.S. 469, 472-73 (1962).

80. To the extent facts underlying issues tried to a jury have "substantial commonality" with facts that underlie equitable defenses, the Seventh Amendment constrains the Court's subsequent factual determinations. *Cabinet Vision v. Cabnetware*, 129 F.3d 595, 600 (Fed. Cir. 1997).

81. A patent challenger who would not have been entitled to a jury trial on a § 256 inventorship claim, standing alone, when a fraud claim was asserted, required a jury to determine facts that were common to the inventorship and fraud issues. *Shum v. Intel, Corp.* 499 F.3d 1272, 1279 (Fed. Cir. 2007).

B. Unclean Hands

82. The doctrine of unclean hands arises from the maxim, "He who comes into equity must come with clean hands." *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 241 (1933).

83. As applied to patents, unclean hands stems from three Supreme Court decisions, namely: *Keystone*, *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944), *overruled on other grounds by Standard Oil Co. v. U.S.*, 429 U.S. 17 (1976), and *Precision Instrument manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945).

84. In *Keystone*, the suitor in equity had manufactured and suppressed evidence. *See*

Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1285 (Fed. Cir. 2011)(en banc).

85. *Hazel-Atlas* also involved the manufacture and suppression of evidence by the suitor in equity. *See Therasense*, 649 F.3d at 1286.

86. In *Precision*, the suitor in equity suppressed evidence of perjury before the PTO and attempted to enforce the perjury-tainted patent. *Therasense*, 649 F.3d at 1286.

87. *Keystone*, *Hazel-Atlas*, and *Precision*, dealt with particularly egregious misconduct, including perjury, the manufacture of false evidence, and the suppression of evidence. *See Therasense*, 649 F.3d at 1287.

88. The doctrine of inequitable conduct evolved from these unclean hands cases and came to embrace a broader scope of misconduct, including not only egregious affirmative acts of misconduct intended to deceive both the PTO and the courts, but also the mere nondisclosure of information to the PTO. *Therasense*, 649 F.3d at 1287.

89. Inequitable conduct requires clear and convincing evidence of both (i) the materiality of the wrongful act or omission, and (ii) a specific intent to deceive the PTO. *Therasense*, 649 F.3d at 1290.

90. Though inequitable conduct developed from these unclean hands cases, "the unclean hands doctrine remains available to supply a remedy for egregious misconduct like that in the Supreme Court cases. *Therasense*, 649 F.3d at 1290.

91. Whereas inequitable conduct in prosecuting a patent may result in the patent being held unenforceable, a finding of unclean hands has more limited consequences. In *Keystone*, the Supreme Court affirmed a decision by the Sixth Circuit that directed the district court to dismiss Keystone's complaints without prejudice. 290 U.S. at 244.

92. In *Keystone*, the Court of Appeals carefully to prescribed the limits of its holding that the Supreme Court later affirmed: "The decrees of the District Court are reversed, and the causes are remanded, with instructions to dismiss the bills of complaint without prejudice to the prosecution of suits at law, or, indeed, to subsequent actions in equity upon the other patents in suit." *Gen. Excavator Co. v. Keystone Driller Co.*, 62 F.2d 48, 51 (6th Cir. 1932).

93. In cases where unclean hands arose from egregious misconduct in litigation, the Federal Circuit has affirmed dismissal of the action in which the misconduct occurred, but reversed the trial

court's ruling that unclean hands rendered the patent unenforceable. *Aptix Corp. v. Quickturn Design Sys., Inc.*, 269 F.3d 1369, 1371, 1373 (Fed. Cir. 2001).

94. In affirming dismissal of patent infringement action for unclean hands where the patentee had submitted falsified engineering notebooks to the court the court emphasized that the doctrine does not reach out to extinguish a property right based on misconduct during litigation to enforce the right. *Aptix*, 269 F.3d at 1375.

95. It is fundamental to the operation of the doctrine that the alleged misconduct of the party relate directly to the transaction concerning which the complaint is made. *Seller Agency v. Kennedy Center For Real Estate*, 621 F.3d 981, 987 (9th Cir. 2010).

96. Unclean hand must be proved by clean and convincing evidence, *In re Omeprazole Patent Litig.*, 483 F.3d 1364, 1374 (Fed. Cir. 2007), is within the discretion of the trial court, and is reviewed for abuse of that discretion. *Seller*, 621 F.3d at 986; *Aptix*, 269 F.3d at 1374.

97. It is well settled that there is nothing improper, illegal or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor's product from the market; nor is it in any manner improper to amend or insert claims intended to cover a competitor's product the applicant's attorney has learned about during the prosecution of a patent application. *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 874 (Fed. Cir. 1988).

98. If any such amendment complies with all statutes and regulations, its genesis in the marketplace is simply irrelevant and cannot of itself evidence deceitful intent. O*rmco Corp. v. Align Technology, Inc.*, 647 F. Supp. 2d 1200, 1207 (C.D. Cal. 2009).

99. That the patent owner knew of the accused infringer's processes and filed claims that covered these processes did not support a finding of unclean hands. (applying *Kingsdown*); *Laitram Corp. v. Morehouse Indus., Inc.*, No S-94-0452, 1997 WL 33320572, at *13 (E.D. Cal. Apr. 24, 1997).

100. Amendments to cover competitors' products are entirely appropriate so long as supported by the original disclosure. *Laitram Corp. v. Morehouse Indus., Inc.*, 143 F.3d 1456 (Fed. Cir. 1998).

C. Waiver

101. Courts have recognized waiver as a cognizable defense to a charge of patent infringement. *Qualcomm Inc. v. Broadcom Corp.*, 548 F.3d 1004, 1019 (Fed. Cir. 2008).

102. True waiver requires a voluntary or intentional relinquishment of a known right. *Qualcomm*, 548 F.3d at 1019.

103. A defense of waiver requires a showing of intentional relinquishment of a known right. *Barnes & Noble, Inc. v. LSI Corp.*, 849 F.Supp.2d 925, 941 (N.D. Cal. 2012) (quoting *U.S. v. Perez*, 116 F.3d 840, 845 (9th Cir. 1997).

104. In the alternative, courts have recognized a defense of implied waiver in the context of standard-setting organization where (1) the patentee had a duty of disclosure to the standard setting organization and (2) the patentee had breached that duty. *Barnes & Noble*, 849 F.Supp.2d at 941-42. (citing *Hynix Semiconductor Inc. v. Rambus, Inc.*, 645 F.3d 1336, 1348 (Fed. Cir. 2011).

105. Courts have found implied waiver for breach of duty of disclosure to standard-setting organizations. *Qualcomm Inc. v. Broadcom Corp.*, No. Civ. 05CV1958-B(BLM), 2007 WL 1031373, at *6-23 (S.D. Cal. Mar. 21, 2007), *aff'd* 548 F.3d at 1020-22.

106. Waiver must be shown by clear and convincing evidence. *Qualcomm*, 2007 WL 1031373 at *8-9.

Dated: March 22, 2016

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CERTIFICATE OF SERVICE

I certify that all counsel of record are being served on March 22, 2016 with a copy of this document via the Court's CM/ECF system.

/s/ Stephen S. Rabinowitz
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